PENALTY SCHEDULE 1—Continued

Section ²	Violation	Willful violation
(a) Failure to comply with Part 40 procedures in Subpart B, D, F, or G testing(b) Testing not performed in a timely manner	-5,000 2,500	-7,500 5,000
Subpart I—Annual Report		
219.801 Reporting alcohol misuse prevention program results in a management information system:		
(a) Failure to submit MIS report on time	2,500	5,000
(c) Failure to submit accurate MIS report	2,500	5,000
(d) Failure to include required data	2,500	5,000
219.803 Reporting drug misuse prevention program results in a management information system:		
(c) Failure to submit accurate MIS report	2,500	5,000
(d) Failure to submit MIS report on report	2,500	5,000
(e) Failure to include required data	2,500	5,000
Subpart J—Recordkeeping Requirements		
219.901 Retention of Alcohol Testing Records:		
(a) Failure to maintain records required to be kept by Part 40	2.500	5.000
(b) Failure to maintain records required to be kept for five years	2,500	5,000
(c) Failure to maintain records required to be kept for two years	2,500	5,000
219.903 Retention of Drug Testing Records:	,	,
(a) Failure to maintain records required to be kept by Part 40	2,500	5,000
(b) Failure to maintain records required to be kept for five years	2,500	5,000
(c) Failure to maintain records required to be kept for two years	2,500	5,000
219.905 Access to facilities and records:		,
(a) Failure to release records in this subpart in accordance with Part 40	2,500	5,000
(b) Failure to permit access to facilities	2,500	5,000
(c) Failure to provide access to results of railroad alcohol and drug testing programs	2,500	5,000

[66 FR 41973, Aug. 9, 2001, as amended at 69FR 30593, May 28, 2004; 73 FR 79702, Dec. 30,

APPENDIX B TO PART 219—DESIGNATION OF LABORATORY FOR POST-ACCIDENT TOXICOLOGICAL TESTING

The following laboratory is currently designated to conduct post-accident toxicological analysis under subpart C of this part: Northwest Toxicology/LabOne, Hayes Building, Suite #C, 2282 South Presidents Drive, West Valley City, UT 84120, Tele-phone: (800) 322–3361 or (801) 293–2300 (Day), (801) 244-5599 (Night/Weekend).

[70 FR 16966, Apr. 4, 2005]

APPENDIX C TO PART 219—POST-ACCI-DENT TESTING SPECIMEN COLLEC-TION

1.0 General.

This appendix prescribes procedures for collection of specimens for mandatory postaccident testing pursuant to subpart C of this part. Collection of blood and urine specimens is required to be conducted at an independent medical facility.

 $(Surviving\ Employees)$

2.0 Surviving Employees.

This unit provides detailed procedures for collecting post-accident toxicological specimens from surviving employees involved in train accidents and train incidents, as required by subpart C of this part. Subpart C specifies qualifying events and employees required to be tested.

2.1 Collection Procedures; General.

a. All forms and supplies necessary for collection and transfer of blood and urine specimens for three surviving employees can be found in the FRA post-accident shipping box, which is made available to the collection site by the railroad representative.

b. Each shipping box contains supplies for blood/urine collections from three individuals, including instructions and necessary forms. The railroad is responsible for ensuring that materials are fresh, complete and meet FRA requirements.

2.1.1 Responsibility of the Railroad Representative.

a. In the event of an accident/incident for which testing is required under subpart C of this part, the railroad representative shall follow the designated set of instructions, and, upon arrival at the independent medical facility, promptly present to the collection

¹A penalty may be assessed against an individual only for a willful violation. The FRA Administrator reserves the right to assess a penalty of up to \$100,000 for any violation, including ones not listed in this penalty schedule, where circumstances warrant. See 49 CFR part 209, appendix A.
²The penalty schedule uses section numbers from 49 CFR part 219; and if more than one item is listed as a type of violation of a given section, each item is also designated by a "penalty code" (e.g., "A"), which is used to facilitate assessment of civil penalties. For convenience, penalty citations will cite the CFR section and the penalty code, if any (e.g., "Sec. 219.11A") FRA reserves the right, should litigation become necessary, to substitute in its complaint the CFR citation in place of the combined CFR and penalty code citation.

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facility representative a post-accident shipping box or boxes with all remaining sets of instructions. (Each box contains supplies to collect specimens from three employees.) The railroad representative shall request the collection facility representative to review the instructions provided and, through qualified personnel, provide for collection of the specimens according to the procedures set out.

b. The railroad representative shall undertake the following additional responsibilities—

- 1. Complete Form FRA 6180.73 (revised), Accident Information Required for Post-Accident Toxicological Testing (49 CFR part 219), describing the testing event and identifying the employees whose specimens are to be deposited in the shipping box.
- 2. As necessary to verify the identity of individual employees, affirm the identity of each employee to the medical facility personnel.
- 3. Consistent with the policy of the collection facility, monitor the progress of the collection procedure.

Warning: Monitor but do not directly observe urination or otherwise disturb the privacy of urine or blood collection. Do not handle specimen containers, bottles or tubes (empty or full). Do not become part of the collection process.

2.1.2 Employee Responsibility.

- a. An employee who is identified for postaccident toxicological testing shall cooperate in testing as required by the railroad and personnel of the independent medical facility. Such cooperation will normally consist of the following, to be performed as requested:
- 1. Provide a blood specimen, which a qualified medical professional or technician will draw using a single-use sterile syringe. The employee should be seated for this procedure.
- 2. Provide, in the privacy of an enclosure, a urine specimen into a plastic collection cup. Deliver the cup to the collector.
- Do not let the blood and urine specimens that you provided leave your sight until they have been properly sealed and initialed by you.
- 4. Certify the statement in Step 4 of the Post-Accident Testing Blood/Urine Custody and Control Form (49 CFR part 219) (Form FRA F 6180.74 (revised)).
- 5. If required by the medical facility, complete a separate consent form for taking of the specimens and their release to FRA for analysis under the FRA rule.

NOTE: The employee may not be required to complete any form that contains any waiver of rights the employee may have in the employment relationship or that releases or holds harmless the medical facility with respect to negligence in the collection.

 $2.2 \quad The \ Collection.$

Exhibit C-1 contains instructions for collection of specimens for post-accident toxicology from surviving employees. These instructions shall be observed for each collection. Instructions are also contained in each post-accident shipping box and shall be provided to collection facility personnel involved in the collection and/or packaging of specimens for shipment. (Post Mortem Collection)

$3.0 \quad Fatality.$

This unit provides procedures for collecting post-accident body fluid/tissue specimens from the remains of employees killed in train accidents and train incidents, as required by subpart C of this part. Subpart C specifies qualifying events and employees required to be tested.

3.1 Collection.

In the event of a fatality for which testing is required under Subpart C of this part, the railroad shall promptly make available to the custodian of the remains a post-accident shipping box. The railroad representative shall request the custodian to review the instructions contained in the shipping box and, through qualified medical personnel, to provide the specimens as indicated.

(Surviving Employees and Fatalities)

4.0 Shipment.

- a. The railroad is responsible for arranging overnight transportation of the sealed shipping box containing the specimens. When possible without incurring delay, the box should be delivered directly from the collection personnel providing the specimens to an overnight express service courier. If it becomes necessary for the railroad to transport the box from point of collection to point of shipment, then—
- 1. Individual kits and the shipping box shall be sealed by collection personnel before the box is turned over to the railroad representative;
- 2. The railroad shall limit the number of persons handling the shipping box to the minimum necessary to provide for transportation:
- 3. If the shipping box cannot immediately be delivered to the express carrier for transportation, it shall be maintained in secure temporary storage; and
- 4. The railroad representatives handling the box shall document chain of custody of the shipping box and shall make available such documentation to FRA on request.

EXHIBIT C-1—INSTRUCTIONS FOR COLLECTION OF BLOOD AND URINE SPECIMENS: MANDA-TORY POST-ACCIDENT TOXICOLOGICAL TEST-ING

A. Purpose

These instructions are for the use of personnel of collection facilities conducting collection of blood and urine specimens from

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surviving railroad employees following railroad accidents and casualties that qualify for mandatory alcohol/drug testing. The Federal Railroad Administration appreciates the participation of medical facilities in this important public safety program.

B. Prepare for Collection

- a. Railroad employees have consented to provision of specimens for analysis by the Federal Railroad Administration as a condition of employment (49 CFR 219.11). A private, controlled area should be designated for collection of specimens and completion of paperwork.
- b. Only one specimen should be collected at a time, with each employee's blood draw or urine collection having the complete attention of the collector until the specific specimen has been labeled, sealed and documented.
- c. Please remember two critical rules for the collections:
- d. All labeling and sealing must be done in the sight of the donor, with the specimen never having left the donor's presence until the specimen has been labeled, sealed and initialed by the donor.
- e. Continuous custody and control of blood and urine specimens must be maintained and documented on the forms provided. In order to do this, it is important for the paperwork and the specimens to stay together.
- f. To the extent practical, blood collection should take priority over urine collection. To limit steps in the chain of custody, it is best if a single collector handles both collections from a given employee.
- g. You will use a single Post-Accident Testing Blood/Urine Custody and Control Form (FRA Form 6108.74 (revised)), consisting of six Steps to complete the collection for each employee. We will refer to it as the Control Form.

C. Identify the Donor

- a. The employee donor must provide photo identification to each collector, or lacking this, be identified by the railroad representative.
- b. The donor should remove all unnecessary outer garments such as coats or jackets, but may retain valuables, including a wallet. Donors should not be asked to disrobe, unless necessary for a separate physical examination required by the attending physician.

D. Draw Blood

- a. Assemble the materials for collecting blood from each employee: two 10 ml greystoppered blood tubes and the Control Form.
- b. Ask the donor to complete STEP 1 on the Control Form.
- c. With the donor seated, draw two (2) 10 ml tubes of blood using standard medical

procedures (sterile, single-use syringe into evacuated gray-top tubes provided). CAUTION: Do not use alcohol or an alcohol-based swab to cleanse the venipuncture site.

- d. Once both tubes are filled and the site of venipuncture is protected, immediately—
- 1. Seal and label each tube by placing a numbered blood specimen label from the label set on the Control Form over the top of the tube and securing it down the sides.
- 2. Ask the donor to initial each label. Please check to see that the initials match the employee's name and note any discrepancies in the "Remarks" block of the Control Form.
- 3. As collector, sign and date each blood tube label at the place provided.
- 4. Skip to STEP 5 and initiate chain of custody for the blood tubes by filling out the first line of the block to show receipt of the blood specimens from the donor.
- 5. Complete STEP 2 on the form.
- 6. Return the blood tubes into the individual kit. Keep the paperwork and specimens together. If another collector will be collecting the urine specimen from this employee, transfer both the form and the individual kit with blood tubes to that person, showing the transfer of the blood tubes on the second line of STEP 5 (the chain of custody block).

$E.\ Collect\ Urine$

- a. The urine collector should assemble at his/her station the materials for collecting urine from each employee: one plastic collection cup with temperature device affixed enclosed in a heat-seal bag (with protective seal intact), two 90 ml urine specimen bottles with caps and one biohazard bag (with absorbent) also enclosed in a heat-seal bag (with protective seal intact), and the Control Form. Blood specimens already collected must remain in the collector's custody and control during this procedure.
- b. After requiring the employee to wash his/her hands, the collector should escort the employee directly to the urine collection area. To the extent practical, all sources of water in the collection area should be secured and a bluing agent (provided in the box) placed in any toilet bowl, tank, or other standing water.
- c. The employee will be provided a private place in which to void. Urination will not be directly observed. If the enclosure contains a source of running water that cannot be secured or any material (soap, etc.) that could be used to adulterate the specimen, the collector should monitor the provision of the specimen from outside the enclosure. Any unusual behavior or appearance should be noted in the remarks section of the Control Form or on the back of that form.
- d. The collector should then proceed as follows:

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- e. Unwrap the collection cup in the employee's presence and hand it to the employee (or allow the employee to unwrap it).
- f. Ask the employee to void at least 60 ml into the collection cup (at least to the line marked).
- g. Leave the private enclosure.
- IF THERE IS A PROBLEM WITH URINATION OR Specimen QUANTITY, SEE THE "TROUBLE BOX" AT THE BACK OF THESE INSTRUCTIONS.
- h. Once the void is complete, the employee should exit the private enclosure and deliver the specimen to the collector. Both the collector and the employee must proceed immediately to the labeling/sealing area, with the specimen never leaving the sight of the employee before being sealed and labeled.
- i. Upon receipt of the specimen, proceed as follows:
- 1. In the full view of the employee, remove the wrapper from the two urine specimen bottles. Transfer the urine from the collection cup into the specimen bottles (at least 30 ml in bottle A and at least 15 ml in bottle B).
- 2. As you pour the specimen into the specimen bottles, please inspect for any unusual signs indicating possible adulteration or dilution. Carefully secure the tops. Note any unusual signs under "Remarks" at STEP 3 of the Control Form.
- 3. Within 4 minutes after the void, measure the temperature of the urine by reading the strip on the bottle. Mark the result at STEP 3 of the Control Form.
- IF THERE IS A PROBLEM WITH THE URINE Specimen, SEE THE "TROUBLE BOX" AT THE BACK OF THESE INSTRUCTIONS.
- 4. Remove the urine bottle labels from the Control Form. The labels are marked "A" and "B." Place each label as marked over the top of its corresponding bottle, and secure the label to the sides of the bottle.
- 5. Ask the donor to initial each label. Please check to see that the initials match the employee name and note any discrepancy in the "Remarks" block of STEP 3.
- 6. As collector, sign and date each urine label.
- 7. Skip to STEP 5 and initiate chain-ofcustody by showing receipt of the urine specimens from the donor. (If you collected the blood, a check under "urine" will suffice. If someone else collected the blood, first make sure transfer of the blood to you is documented. Then, using the next available line, show "Provide specimens" under purpose, "Donor" under "released by," check under "urine" and place your name, signature and date in the space provided.)
- 8. Complete the remainder of STEP 3 on the Control Form.
- 9. Have the employee complete STEP 4 on the Control Form.

10. Place the filled urine bottles in the individual employee kit. Keep the paperwork and specimens together. If another collector will be collecting the blood specimen from this employee, transfer both the form and the kit to that person, showing the transfer of the urine specimens on the next available line of STEP 5 (the chain of custody block).

F. Seal the Individual Employee Kit

- a. The blood and urine specimens have now been collected for this employee. The blood/ urine specimens will now be sealed into the individual employee kit, while all paperwork will be retained for further completion. After rechecking to see that each specimen is properly labeled and initialed, close the plastic bag to contain any leakage in transportation, and apply the kit security seal to the small individual kit. As collector, sign and date the kit seal.
- b. Before collecting specimens from the next employee, complete the next line on the chain-of-custody block showing release of the blood and urine by yourself for the purpose of "Shipment" and receipt by the courier service or railroad representative that will provide transportation of the box, together with the date.

G. Complete Treatment Information

Complete STEP 6 of the Control Form. Mark the box if a breath alcohol test was conducted under FRA authority.

H. Prepare the Box for Shipment

- a. Sealed individual employee kits should be retained in secure storage if there will be a delay in preparation of the shipping box. The shipping box shall be prepared and sealed by a collection facility representative as follows:
- 1. Inspect STEP 5 of each Control Form to ensure chain-of-custody is continuous and complete for each fluid (showing specimens released for shipment). Retain the medical facility copy of each Control Form and the Accident Information form for your records.
- 2. Place sealed individual employee kits in the shipping box. Place all forms in zip-lock bag and seal securely. Place bag with forms and unused supplies in shipping box.
- 3. Affix the mailing label provided to the outside of the shipping box.

I. Ship the Box

- a. The railroad must arrange to have the box shipped overnight air express or (if express service is unavailable) by air freight, prepaid, to FRA's designated laboratory. Whenever possible without incurring delay, the collector should deliver the box directly into the hands of the express courier or air freight representative.
- b. Where courier pickup is not immediately available at the collection facility

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where the specimens are taken, the railroad is required to transport the shipping box for expeditious shipment by air express, air freight or equivalent means.

c. If the railroad is given custody of the box to arrange shipment, please record the name of the railroad official taking custody on the copy of Form 6180.73 retained by the collection site.

"TROUBLE BOX"

1. Problem: The employee claims an inability to urinate, either because he/she has recently voided or because of anxiety concerning the collection

Action: The employee may be offered moderate quantities of liquid to assist urination. If the employee continues to claim inability after 4 hours, the urine collection should be discontinued, but the blood specimens should be forwarded and all other procedures followed. Please note in area provided for remarks what explanation was provided by the employee.

2. Problem: The employee cannot provide approximately 60 ml. of specimen.

Action: The employee should remain at the collection facility until as much as possible of the required amount can be given (up to 4 hours). The employee should be offered moderate quantities of liquids to aid urination. The first bottle, if it contains any quantity of urine, should be sealed and securely stored with the blood tubes and Control Form pending shipment. A second bottle should then be used for the subsequent void (using a second Control Form with the words "SECOND VOID—FIRST Specimen INSUFFICIENT" in the remarks block and labels from that form). However, if after 4 hours the donor's second void is also insufficient or contains no more than the first insufficient void, discard the second void and send the first void to the laboratory.

- 3. Problem: The urine temperature is outside the normal range of 32 deg.—38 deg.C/90 deg.—100 deg.F, and a suitable medical explanation cannot be provided by an oral temperature or other means; or
- 4. Problem: The collector observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the specimen (e.g., substitute urine in plain view, blue dye in specimen presented, etc.) and a collection site supervisor or the railroad representative agrees that the circumstances indicate an attempt to tamper with the specimen.

Action (for either Problem No. 3 or Problem No. 4): Document the problem on the Control Form.

i. If the collection site supervisor or railroad representative concurs that the temperature of the specimen, or other clear and unequivocal evidence, indicates a possible attempt to substitute or alter the specimen, another void must be taken under direct observation by a collector of the same gender.

ii. If a collector of the same sex is not available, do NOT proceed with this step.

iii. If a collector of the same gender is available, proceed as follows: A new Control Form must be initiated for the second void. The original suspect specimen should be marked "Void" and the follow-up void should be marked "Void 2," with both voids being sent to the laboratory and the incident clearly detailed on the Control Form.

EXHIBIT C-2—INSTRUCTIONS FOR COLLECTION OF POST MORTEM SPECIMENS: EMPLOYEE KILLED IN A RAILROAD ACCIDENT/INCIDENT

To the Medical Examiner, Coroner, or Pathologist:

- a. In compliance with Federal safety regulations (49 CFR Part 219), a railroad representative has requested that you obtain specimens for toxicology from the remains of a railroad employee who was killed in a railroad accident or incident. The deceased consented to the taking of such specimens, as a matter of Federal law, by performing service on the railroad (49 CFR 219.11(f)).
- b. Your assistance is requested in carrying out this program of testing, which is important to the protection of the public safety and the safety of those who work on the railroads.

A. Materials:

The railroad will provide you a post-accident shipping box that contains necessary supplies. If the box is not immediately available, please proceed using supplies available to you that are suitable for forensic toxicology.

- B. Specimens requested, in order of preference:
- a. Blood—20 milliliters or more. Preferred sites: intact femoral vein or artery or peripheral vessels (up to 10 ml, as available) and intact heart (20 ml). Deposit blood in gray-stopper tubes individually by site and shake to mix specimen and preservative.

NOTE: If uncontaminated blood is not available, bloody fluid or clots from body cavity may be useful for qualitative purposes; but do not label as blood. Please indicate source and identity of specimen on label of tube.

- b. Urine—as much as 100 milliliters, if available. Deposit into plastic bottles provided.
- c. Vitreous fluid—all available, deposited into smallest available tube (e.g., 3 ml) with 1% sodium fluoride, or gray-stopper tube (provided). Shake to mix specimen and preservative.
- d. If available at autopsy, organs—50 to 100 grams each of two or more of the following in order preference, as available: liver, bile, brain, kidney, spleen, and/or lung. Specimens should be individually deposited into zip-

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lock bags or other clean, single use containers suitable for forensic specimens.

- e. If vitreous or urine is not available, please provide—
- 1. Spinal fluid—all available, in 8 ml container (if available) with sodium fluoride or in gray-stopper tube; or, if spinal fluid cannot be obtained,
- 2. Gastric content—up to 100 milliliters, as available, into plastic bottle.

C. Specimen collection:

- a. Sampling at time of autopsy is preferred so that percutaneous needle puncturing is not necessary. However, if autopsy will not be conducted or is delayed, please proceed with sampling.
- b. Blood specimens should be taken by sterile syringe and deposited directly into evacuated tube, if possible, to avoid contamination of specimen or dissipation of volatiles (ethyl alcohol).

NOTE: If only cavity fluid is available, please open cavity to collect specimen. Note condition of cavity.

c. Please use smallest tubes available to accommodate available quantity of fluid specimen (with 1% sodium fluoride).

D. Specimen identification, sealing:

- a. As each specimen is collected, seal each blood tube and each urine bottle using the respective blood tube or urine bottle using the identifier labels from the set provided with the Post-Accident Testing Blood/Urine Custody and Control Form (49 CFR part 219) (Form FRA F 6180.74 (revised)). Make sure the unique identification number on the labels match the pre-printed number on the Control Form. Please label other specimens with name and specimen set identification numbers. You may use labels and seals from any of the extra forms, but annotate them accordingly.
- b. Annotate each label with specimen description and source (as appropriate) (e.g., blood, femoral vein).
- c. Please provide copy of any written documentation regarding condition of body and/or sampling procedure that is available at the time specimens are shipped.

E. Handling:

- a. If specimens cannot be shipped immediately as provided below, specimens other than blood may be immediately frozen. Blood specimens should be refrigerated, but not frozen.
- b. All specimens and documentation should be secured from unauthorized access pending delivery for transportation.

F. Information:

a. If the railroad has not already done so, please place the name of the subject at the top of the Control Form (STEP 1). You are

requested to complete STEP 2 of the form, annotating it by writing the word "FATAL-ITY," listing the specimens provided, providing any further information under "Remarks" or at the bottom of the form. If it is necessary to transfer custody of the specimens from the person taking the specimens prior to preparing the box for shipment, please use the blocks provided in STEP 5 to document transfer of custody.

b. The railroad representative will also provide Accident Information Required for Post-Accident Toxicological Testing (49 CFR part 219), Form FRA 6180.73 (revised). Both forms should be placed in the shipping box when completed; but you may retain the designated medical facility copy of each form for your records.

G. Packing the shipping box:

- a. Place urine bottles and blood tubes in the sponge liner in the individual kit, close the biohazard bag zipper, close the kit and apply the kit custody seal to the kit. You may use additional kits for each tissue specimen, being careful to identify specimen by tissue, name of deceased, and specimen set identification number. Apply kit security seals to individual kits and initial across all seals. Place all forms in the zip-lock bag and seal securely.
- b. Place the bag in the shipping box. Do not put forms in with the specimens. Seal the shipping box with the seal provided and initial and date across the seal.
- c. Affix the mailing label to the outside of the box.

H. Shipping the box:

- a. The railroad must arrange to have the box shipped overnight air express or (if express service is unavailable) by air freight, prepaid, to FRA's designated laboratory. When possible, but without incurring delay, deliver the sealed shipping box directly to the express courier or the air freight representative.
- b. If courier pickup is not immediately available at your facility, the railroad is required to transport the sealed shipping box to the nearest point of shipment via air express, air freight or equivalent means.
- c. If the railroad receives the sealed shipping box to arrange shipment, please record under "Supplemental Information" on the Control Form, the name of the railroad official taking custody.

I. Other:

FRA requests that the person taking the specimens annotate the Control Form under "Supplemental Information" if additional toxicological analysis will be undertaken with respect to the fatality. FRA reports are available to the coroner or medical examiner on request.